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jc928 U.S. PTO

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DATED: October 10, 2001

ATTY DOCKET: FSTK 1004-1

jc971 U.S. PTO
09/974781
10/10/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Commissioner of Patents
Washington, D.C. 20231

Sir:

UTILITY PATENT APPLICATION TRANSMITTAL LETTER

Enclosed for filing is [] an original patent application or, [X] a continuation-in-part patent application by **MICHAEL G. KAHN, CAROL A. BROVERMAN and KELLY A. KINGDON** for **IMPROVING CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY.**

Also enclosed are:

- [X] Forty-one (41) sheet(s) of [] formal [X] informal drawings;
 - [X] Fifty-four (54) sheets of specification, claims and abstract;
 - [X] Application Data Sheet;
 - [X] **Request for Non-Publication Under 35 USC 122(b)(2)(B)(i);**
- In addition:
- [X] **Applicant claims small entity status.**

Please defer the filing fee at this time.

Date: 10 October 2001.

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, CA 94019
(650) 712-0340-phone
(650) 712-0263-fax

Respectfully submitted,

By: Warren S. Wolfeld
Warren S. Wolfeld, Reg. No. 31,454

CUSTOMER NO. 22470

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**REQUEST AND CERTIFICATION
UNDER
35 U.S.C. 122(b)(2)(B)(i)**

First Named Inventor MICHAEL G. KAHN

Title Improving Clinical Trial Protocol Quality Using A
Model-Based Methodology

Atty Docket Number FSTK 1004-1US

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. I hereby request that the attached application not be published under 35 U.S.C. 122(b).

10/10/2001

Date

Warren S. Wolfeld

Signature

WARREN S. WOLFELD

Typed or printed name

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing**.

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

Burden Hour Statement: This collection of information is required by 37 CFR 1.213(a). The information is used by the public to request that an application not be published under 35 U.S.C. 122(b) (and the PTO to process that request). Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This form is estimated to take 6 minutes to complete. This time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.